In the Claims:

We claim:

1-23. (canceled)

24. (currently amended) A method for characterizing prostate cancer in a subject, comprising:

a) providing a sample from a subject, wherein said subject has been diagnosed with prostate cancer; and

b) characterizing said sample by detecting the presence or absence of HIP1 in said sample with a nucleic acid probe configured to hybridize to a HIP1 nucleic acid sequence consisting of the nucleic acid sequence of SEQ ID NO:1, wherein said presence or absence of HIP1 in said sample is indicative of one or more of properties of said cancer selected from the group consisting of ~~risk of prostate specific antigen failure, risk of said cancer metastasizing, risk of said cancer recurring~~, PSA recurrence, recurrence free survival, and stage of said cancer.

25. (previously presented) The method of Claim 24, wherein said sample is tumor tissue.

26. (previously presented) The method of Claim 24, wherein said sample is biopsy tissue.

27. (original) The method of Claim 24, wherein said detecting HIP1 comprises detecting the presence of HIP1 mRNA.

28. (canceled)

29. (previously presented) The method of Claim 24, wherein said detecting the presence of HIP1 mRNA comprises a detection assay selected from the group consisting of a Northern blot, in situ hybridization, reverse-transcriptase polymerase chain reaction, and microarray analysis.

30-35. (canceled)

36. (previously presented) The method of Claim 24, wherein said stage of said cancer is selected from the group consisting of high-grade prostatic intraepithelial neoplasia, benign prostatic hyperplasia, prostate carcinoma, and metastatic prostate carcinoma.

37-83. (canceled)

84. (withdrawn) The method of Claim 9, wherein said reagent is configured to detect an ENTH deletion mutant of said HIP1.

85. (withdrawn) The method of Claim 9, wherein said reagent is configured to detect SEQ ID NO:4.

86. (withdrawn) The method of Claim 9, wherein said reagent is configured to detect an ENTH domain of said HIP1.

87-90. (canceled)

91. (withdrawn) The method of Claim 24, wherein said reagent is configured to detect an ENTH deletion mutant of said HIP1.

92. (withdrawn) The method of Claim 24, wherein said reagent is configured to detect SEQ ID NO:4.

93. (withdrawn) The method of Claim 24, wherein said reagent is configured to detect an ENTH domain of said HIP1.

94. (canceled)

95. (previously presented) The method of claim 24, wherein said probe is a primer.

REMARKS

Claims 24-27, 29, 36, 84-86, 91-93 and 95 are pending in the present application. Claims 24-27, 29, 36, and 95 stand rejected by the Examiner.

The Applicants note that all amendments of Claims presented herein are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),[1] and without waiving the right to prosecute the amended Claims (or similar Claims) in the future.

I. CLAIM REJECTIONS UNDER 35 U.S.C. §112, FIRST PARAGRAPH

The Examiner has rejected Claims 24-27, 29, 36 and 95 under 112, first paragraph, as allegedly lacking enablement (Office Action, pg. 2). In particular, the Examiner states "The instant specification is not enabling for claims drawn a [sic] method of characterizing prostate cancer by measuring the absence or presence of HIP1 in a sample, wherein the absence or presence of HIP1 is indicative of prostate specific failure, the risk of prostate cancer metastasizing, the risk of prostate cancer reoccurring or the stage of cancer." (Office Action, pg. 3).

The Applicants respectfully disagree with the rejection. Nonetheless, In order to further the business interests of the Applicants and while reserving the right to prosecute the original (or similar) claims in the future, the Applicants have amended Claim 24 to include the elements of PSA recurrence, recurrence free survival and state of cancer. As stated by the Examiner, the specification teaches "HIP1 expression in individual patients reveals that there were progressively higher frequencies of HIP1 expression in benign, PIN, PCA and metastaic case." (Office Action, pgs. 3-4) and "Moreover, the specification teaches the clinical implications associated with HIP1 expression, wherein patients with tumors which did not stain for HIP1 expression did not develop a PSA recurrence." (Office Action, pg. 4). The Applicants further direct the Examiner to the specification at page 66, lines 9-14, which states:

[1] 65 Fed. Reg. 54603 (Sept. 8, 2000).

> "This is termed PSA recurrence. Patients whose tumors did not stain for HIP1 expression did not develop a PSA recurrence (Table 1). In comparison a preoperative PSA of <4 (normal) compared to PSA> 4 was also a significant good prognostic factor (Pearson's chi-squared; P<0.034). The ability of a HIP1 negative tumor to predict recurrence free survival, also termed negative predictive value was 100% while PSA<4 was 95.6% predictive." (pg. 66, lines 9-14).

The Applicants submit that practice of the present invention does not require undue experimentation. The specification provides substantial experimental guidance, including working examples. The level of skill in the art is high, as other protein and nucleic acid based gene expression assays for cancer exist. The claims are directed to the detection of a specific HIP1 sequence and to specific clinical and diagnostic outcomes. Accordingly, the Applicants submit that the presently claimed invention is enabled and respectfully request that the rejection be withdrawn.

CONCLUSION

Applicant's respectfully request that Claims 24-27, 29, 36 and 95 be passed to allowance and issued as currently written.

If a telephone interview would aid in the prosecution of this application, the Examiner is encouraged to call the undersigned collect at (618) 218-6900.

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